

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JFW

Applicant(s): OSULLIVAN
Serial No.: 10/822,533
Filed: April 12, 2004
Title: BIFIDOBACTERIA AND SIDEROPHORES PRODUCED THEREBY AND METHODS OF USE
Group Art Unit: 1632
Examiner: Unknown
Docket No.: 110.01290102
Confirmation No.: 3326

Commissioner for Patents
Mail Stop Amendment
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

- ☒ Small entity status is entitled to be asserted in the above-identified application.
☒ An itemized return postcard.
☐ A Petition for Extension of Time for __ month(s) and a check in the amount of \$__ for the required fee.
☒ An Information Disclosure Statement (2 pgs); 1449 forms (7 pgs).
☐ A check in the amount of \$__, representing ____.
☐ A certified copy of a __ application, Serial No. __, filed ____, the right of priority of which is claimed under 35 U.S.C. §119.
☐ Other: ____.
☐ Amendment ☐ No Additional fee is required. ☐ The fee has been calculated as shown:

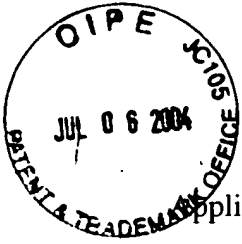
Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$9 =	
Independent Claims				x \$43 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$145 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 2 day of July, 2004.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By:
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PATENT
Docket No. 110.01290102

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Confirmation No.: 3326)
Filed: April 12, 2004)
For: BIFIDOBACTERIA AND SIDEROPHORES PRODUCED THEREBY AND
METHODS OF USE)

Group Art Unit: 1632
Examiner: Unknown

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Mail Stop Amendment
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. §609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 forms is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the 1449 forms, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

This application is a divisional of U.S. Patent Application Serial No. 09/884,894, filed June 19, 2001, U.S. Patent No. 6,746,672. In accordance with 37 C.F.R. §1.98(d), copies of documents previously cited by or submitted to the U.S. Patent and Trademark Office in connection with Applicant's prior application(s) listed above, are not included herewith. In addition, as this patent application was filed after June 30, 2003, copies of the U.S. patents and U.S. patent application publications not previously cited, but listed on the attached 1449 form(s), are not included herewith.

Information Disclosure Statement

Page 2 of 2

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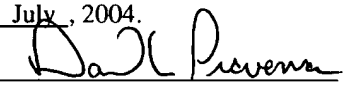
For: BIFIDOBACTERIA AND SIDEROPHORES PRODUCED THEREBY AND METHODS OF USE

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicant's Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 2 day of July, 2004.


David L. Provence

Date

July 2, 2004

DLP/skd

Respectfully submitted for

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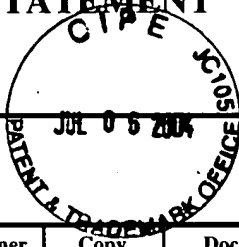


David L. Provence

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	Application Filing Date: April 12, 2004	Group: 1632
	Information Disclosure Statement mailed: <i>July 2, 2004</i>	



U.S. PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		2,785,108	03/12/57	Hawley			
		2,935,503	05/03/60	Hawley et al.			
		4,087,559	05/02/78	Mutai et al.			
		4,091,117	05/23/78	Mutai et al.			
		4,716,115	12/29/87	Gonzalez et al.			
		5,173,297	12/22/92	Vedamuthu et al.			
		5,294,458	03/15/94	Fujimori			
		5,340,577	03/23/94	Nisbet et al.			
		5,494,664	02/27/96	Brassart et al.			
		5,520,936	05/28/96	Delespaul et al.			
		5,594,103	01/14/97	De Vos et al.			
		5,602,109	02/11/97	Masor et al.			
		5,700,590	12/23/97	Masor et al.			
		5,753,614	05/19/98	Blackburn et al.			
		5,776,524	07/07/98	Reinhart			
		5,837,238	11/17/98	Casas et al.			
		5,877,272	03/02/99	Vandenberg			
		5,902,578	05/11/99	Halpin-Dohnalek et al.			
		5,902,743	05/11/99	Lunchansky et al.			
		5,922,375	07/13/99	Luchansky et al.			
		5,952,314	09/14/99	DeMichele et al.			
		5,968,569	10/19/99	Cavadini et al.			
		5,972,415	10/26/99	Brassart et al.			

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Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		6,077,824	06/20/00	English et al.			
		6,746,672 B2	06/08/04	O'Sullivan			

FOREIGN PATENT DOCUMENTS


Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
		American Type Culture Collection, "ATCC Number 9341," organism: <i>Micrococcus luteus</i> (Schroeter); designation: FDA strain PCI 1001 [online]; Manassas, VA [retrieved on 2002-04-03] from the Internet. Retrieved from the Internet: <URL: http://phage.atcc.org/cgi-bin/searchengine/longview.cgi?view=ba,534636,9341&text=9341 >; 2 pgs.
		American Type Culture Collection, "ATCC Number 29425," organism: <i>Escherichia coli</i> (Migula); designation: K12 [online]; Manassas, VA [retrieved on 2002-04-03] from the Internet. Retrieved from the Internet: <URL: http://phage.atcc.org/cgi-bin/searchengine/longview.cgi?view=ba,5225109,29425&text=k12 >; 1 pg.
		Anderssen et al., "Antagonistic Activity of <i>Lactobacillus plantarum</i> C11: Two New Two-Peptide Bacteriocins, Plantaricins EF and JK, and the Induction Factor Plantaricin A," <i>Appl. Environ. Microbiol.</i> , 1998;64(6):2269-2272.
		Archibald, " <i>Lactobacillus plantarum</i> , an organism not requiring iron," <i>FEMS Microbiol. Letts.</i> , 1983;19:29-32.
		Bezkorovainy et al., "Iron Metabolism in Bifidobacteria," <i>Int. Dairy Journal</i> , 1996;6(10):905-919.
		Bezkorovainy et al., "Aspects of Iron Metabolism in <i>Bifidobacterium Bifidum</i> Var. <i>Pennsylvanicus</i> ," <i>Int. J. Biochem.</i> , 1983;15(3):361-366.

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		Bezkorovainy, "Iron Transport and Utilization by Bifidobacteria," <i>Biochemistry and Physiology of Bifidobacteria</i> , CRC Press, Inc., Boca Raton, FL, 1989:147-176.
		Bollag et al., <i>Protein Methods</i> , Wiley and Sons, Inc., New York, NY, 1996; cover page, title page and table of contents only; 10 pgs.
		Braun, "Effect of Consumption of Human Milk and Other Formulas on Intestinal Bacterial Flora in Infants," <i>Textbook of Gastroenterology and Nutrition in Infancy, Vol. 1</i> , Raven Press, New York, NY; 1981:247-253.
		Breed et al., <i>Bergey's Manual of Determinative Bacteriology</i> , 7 th Edition, The Williams and Wilkins Co., Baltimore, MD, 1957; cover page, title page and table of contents only; 7 pgs.
		de Ruyter et al., "Functional Analysis of Promoters in the Nisin Gene Cluster of <i>Lactococcus lactis</i> ," <i>J. Bacteriol.</i> , 1996;178(12):3434-3439.
		Dodd et al., "Analysis of the genetic determinant for production of the peptide antibiotic nisin," <i>J. Gen. Microbiol.</i> , 1990;136(3):555-566.
		Eijsink et al., "Induction of Bacteriocin Production in <i>Lactobacillus Sake</i> by a Secreted Peptide," <i>J. Bacteriol.</i> , 1996;178(8):2232-2237.
		Engelke et al., "Biosynthesis of the Lantibiotic Nisin: Genomic Organization and Membrane Localization of the NisB Protein," <i>Appl. Environ. Microbiol.</i> , 1992;58(11):3730-3743.
		Engelke et al., "Regulation of Nisin Biosynthesis and Immunity in <i>Lactococcus lactis</i> 6F3," <i>Appl. Environ. Microbiol.</i> , 1994;60(3):814-825.
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	Green, "Case report: fatal anaerobic pulmonary infection due to <i>Bifidobacterium eriksonii</i> ," <i>Postgrad. Med.</i> , 1978;63(3):187-188, 190, 192.	
	Gibson et al., "Regulatory effects of bifidobacteria on the growth of other colonic bacteria," <i>J. Appl. Bacteriol.</i> , 1994;77(4):412-420.	

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		Hansen, "Nisin as a Model Food Preservative," <i>Crit. Rev. Food Sci. Nutr.</i> , 1994;34(1):69-93.
		Ibrihim et al., "Inhibition of <i>Escherichia coli</i> by Bifidobacteria," <i>J. Food Prot.</i> , 1993;56(8):713-715.
		Immonen et al., "The codon usage of the <i>nisZ</i> operon in <i>Lactococcus lactis</i> N8 suggests a non-lactococcal origin of the conjugative nisin-sucrose transposon," <i>DNA Seq.- J. Seq. Map.</i> , 1995;5(4):203-218.
		Klaenhammer, "Genetics of bacteriocins produced by lactic acid bacteria," <i>FEMS Microbiol. Rev.</i> , 1993;12(1-3):39-85.
		Kuipers et al., "Characterization of the nisin gene cluster <i>nisABTCIPR</i> of <i>Lactococcus lactis</i> . Requirement of expression of the <i>nisA</i> and <i>nisI</i> genes for development of immunity," <i>Eur. J. Biochem.</i> , 1993;216(1):281-291.
		Kuipers et al., "Autoregulation of Nisin Biosynthesis in <i>Lactococcus lactis</i> by Signal Transduction," <i>J. Biol. Chem.</i> , 1995;270(45):27299-27304.
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		Mevissen-Verhage et al., "Effect of Iron on Neonatal Gut Flora During the First Three Months of Life," <i>Eur. J. Clin. Microbiol.</i> , 1985;4(3):273-278.
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		Muñoz et al., "Selective Medium for Isolation and Enumeration of <i>Bifidobacterium</i> spp.," <i>Appl. Environ. Microbiol.</i> , 1988;54(7):1715-1718.

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		Neilands, "Molecular Aspects of Regulation of High Affinity Iron Absorption in Microorganisms," <i>Metal-Ion Induced Regulation of Gene Expression</i> , 1990;8:63-90.
		Neilands et al., "Comparative Biochemistry of Microbial Iron Assimilation," <i>Iron Transport in Microbes, Plants and Animals</i> , Winkelmann et al., Eds.; Weinheim, Germany, 1987:3-33.
		Nes et al., "Biosynthesis of bacteriocins in lactic acid bacteria," <i>Antonie Van Leeuwenhoek</i> , 1996;70(2-4):113-128.
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		O'Sullivan, "Cloning, organization and regulation of genes involved in iron metabolism in fluorescent <i>Pseudomonos</i> spp. with biocontrol potential," Ph.D. thesis, National University of Ireland, Cork, 1989:1-120.
		O'Sullivan et al., "Traits of Fluorescent <i>Pseudomonos</i> spp. Involved in Suppression of Plant Root Pathogens," <i>Microbiol. Rev.</i> , 1992;56(4):662-676.
		O'Sullivan et al., "Tracking of Probiotic Bifidobacteria in the Intestine," <i>Int. Dairy J.</i> , 1998;8:513-525.
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		O'Sullivan, "Screening of Intestinal Microflora for Effective Probiotic Bacteria," <i>J. Agric. Food Chem.</i> , 2001;49(4):1751-1760.
		Oyarzabal et al., "In vitro Fructooligosaccharide Utilization and Inhibition of <i>Salmonella</i> spp. by Selected Bacteria," <i>Poultry Science</i> , 1995;74(9):1418-1425.
		Poupard et al., "Biology of the Bifidobacteria," <i>Bacteriol. Rev.</i> , 1973;37(2):136-165.
		Pretlow et al., "Aberrant Crypts in Human Colonic Mucosa: Putative Preneoplastic Lesions," <i>J. Cell Biochem.</i> , 1992;Suppl. 16G:55-62.
		Rambaud et al., "Dairy products and intestinal flora," <i>Dairy Products in Human Health and Nutrition</i> , Rios et al., Eds., 1994:389-399.

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		Rammelsberg et al., "Antibacterial polypeptides of <i>Lactobacillus</i> species," <i>J. Appl. Bacteriol.</i> , 1990;69:177-184.
		Resnick et al., "Assessment of Bifidobacteria as Indicators of Human Fecal Pollution," <i>Appl. Environ. Microbiol.</i> , 1981;42(3):433-438.
		Rossi et al., "Improved cloning vectors for <i>Bifidobacterium</i> spp.," <i>Lett. Appl. Microbiol.</i> , 1998;26(2):101-104.
		Sambrook et al., <i>Molecular Cloning: A Laboratory Manual, Book 1</i> , Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, 1989; title page, publisher's page and table of contents only; 26 pgs.
		Sanders, "Probiotics," <i>Food Technology</i> , 1999;53(11):67-77.
		Sasaki et al., "Enhanced Resistance of Mice to <i>Escherichia Coli</i> Infection Induced by Administration of Peptidoglycan Derived from <i>Bifidobacterium thermophilum</i> ," <i>J. Vet. Med. Sci.</i> , 1994;56(3):433-437.
		Scardovi, "Genus <i>Bifidobacterium</i> Orla-Jensen 1924, 472 ^{AL} ," <i>Bergey's Manual of Systematic Bacteriology</i> , Vol. 2, Williams & Wilkins, Baltimore, MD, 1986;1418-1434.
		Scardovi et al., "Deoxyribonucleic Acid Homology among the Species of the Genus <i>Bifidobacterium</i> Isolated from Animals," <i>Arch. Mikrobiol.</i> , 1970;72:318-325.
		Shefet et al., "Efficacy of Optimized Nisin-Based Treatments to Inhibit <i>Salmonella Typhimurium</i> and Extend Shelf Life of Broiler Carcasses," <i>J. Food Prot.</i> , 1995;58(10):1077-1082.
		Siegers et al., "Genes Involved in Immunity to the Lantibiotic Nisin Produced by <i>Lactococcus lactis</i> 6F3," <i>Appl. Environ. Microbiol.</i> , 1995;61(3):1082-1089.
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		Steen et al., "Characterization of the Nisin Gene as Part of a Polycistronic Operon of the Chromosome of <i>Lactococcus lactis</i> ATCC 11454," <i>Appl. Environ. Microbiol.</i> , 1991;57(4):1181-1188.

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		Stevens et al., "Nisin Treatment for Inactivation of <i>Salmonella</i> Species and Other Gram-Negative Bacteria," <i>Appl. Environ. Microbiol.</i> , 1991;57(12):3613-3615.
		Topouzian et al., "Iron uptake by <i>Bifidobacterium bifidum</i> var. <i>pennsylvanicus</i> : the effect of sulfhydryl reagents and metal chelators," <i>IRCS Med. Sci.</i> , 1986;14(3):275-276.
		Torres et al., "Haem iron-transport system in enterohaemorrhagic <i>Escherichia coli</i> O157:H7," <i>Mol. Microbiol.</i> , 1997;23(4):825-833.
		United States Department of Health & Human Services, "Nisin Preparation: Affirmation of Gras Status as a Direct Human Food Ingredient," <i>Federal Register</i> , 1988;53(66):11247-11251.
		United States Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Premarket Approval, "Antimicrobial Food Additives – Guidance," 1999, retrieved from the Internet 2001-12-17, Internet URL: < http://www.cfsan.fda.gov/~dms/opa-antg.html >, 9 pgs.
		van der Meer et al., "Characterization of the <i>Lactococcus Lactis</i> Nisin A Operon Genes <i>NisP</i> , Encoding a Subtilisin-Like Serine Protease Involved in Precursor Processing, and <i>NisR</i> , Encoding a Regulatory Protein Involved in Nisin Biosynthesis," <i>J. Bacteriol.</i> , 1993;175(9):2578-2588.
		Woese, "Bacterial Evolution," <i>Microbiol. Rev.</i> , 1987;51(2):221-271.
		Wun et al., "A New Procedure to Enhance <i>fhuF</i> Expression and Siderophore Production" <i>Amer. Soc. for Microb. 100th General Meeting</i> , Los Angeles, CA, 2000; Abstract I-134:p. 411.
		Yamauchi et al., "Antibacterial Activity of Lactoferrin and a Pepsin-derived Lactoferrin Peptide Fragment," <i>Infect. Immun.</i> , 1993;61(2):719-728.
		Yildirim et al., "Characterization and Antimicrobial Spectrum of Bifidocin B, a Bacteriocin Produced by <i>Bifidobacterium bifidum</i> NCFB 1454," <i>J. Food Prot.</i> , 1998;61(1):47-51.

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